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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,219	02/27/2004	Jean-Luc Jestin	248628US0X	5396

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EXAMINER	
WILDER, CYNTHIA B	
ART UNIT	**PAPER NUMBER**
1637	

DATE MAILED: 08/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/787,219	JESTIN ET AL.	
	Examiner	Art Unit	
	Cynthia B. Wilder, Ph.D.	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 October 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-79* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-79* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-22, 78, 79 drawn to a polynucleotide, classified in class 536, subclass 23.1.

II. Claims 23-58, drawn to a polypeptide and kit, classified in class 530, subclass 350.

III. Claims 59-60, drawn to a method for reverse transcribing RNA, classified in class 435, subclass 91.21.

IV. Claims 61-75, drawn to a method of identifying mutant polypeptide, classified in class 435, subclass 7.2.

V. Claims 76-77, drawn to a method of obtaining enzyme, classified in class 435, subclass 7.1.

Sequence Election Requirement Applicant to All Groups

In addition, The Groups I, II and III detailed above reads on patentably distinct sequences, SEQ ID Numbers and distinct mutations. Each sequence is patentably distinct because the sequences are structurally unrelated sequences, and a further restriction is applied to those Groups. Along with the elected invention, Applicant must further elect **two (2) mutations** as recited in the claims 1, 2 or 23, 24 or 39, 40 or 59, 60 **and** one (1) polynucleotide sequence (SEQ ID NO:) **or** one (1) polypeptide sequences (SEQ ID NO:). The sequence election should correspond with the elected mutation. Applicant must specifically identify each of the

corresponding SEQ ID NO: X or SEQ ID NO: Y for the sequence elected along with the corresponding claims.

MPEP 803.04 states:

Nucleotide sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. The sequences are thus deemed to normally constitute independent and distinct inventions within the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence or amino acid sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 eq seq. By statute, "[i}f two or more independent and distinct inventions are claimed in one application, the Commissioner may require the application to be restricted to one of the invention". "35 U.S.C. 121." Pursuant to this statute, the rules provided that "[i]f two or more independent and distinct invention are claimed in a single application, the examiner in his action shall require the Applicant....to elect that invention to which his claim shall be restricted". 37 CFR 1.142(a). See also 37 CFR 1.141(a).

Applicant is advised that examination will be restricted to only the elected SEQ ID NO: and should not to be construed as a species election. Non-elected sequences in multiple sequence claims will be withdrawn from prosecution.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions of I and II are distinct in structure and physicochemical properties. Inventions I is drawn to an isolated polynucleotide whereas invention II is drawn to an isolated polypeptide. Because the isolated nucleic acid is composed of nucleotides and the isolated polypeptide comprise of amino acids, the inventions have different structural and functional properties as well. Furthermore, the different inventions of I and II can be utilized in different methodologies, such that the polypeptide of invention II is used in e.g., ligand binding assays whereas the polynucleotide of Invention I is utilized in e.g., hybridization and amplification assays. The nucleic acid of

invention II is not required to produce the peptide of invention I because the peptide can be isolated directly from nature or chemically synthesized. As such, the searches of the different inventions are not coextensive and would constitute a search burden to the Examiner if searched together.

2. Inventions III, IV and V are unrelated methods. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different designs, modes of operation, and effects (MPEP § 802.01 and § 806.06). In the instant case, the different inventions have different modes of operation resulting in different effects. For example, the method of invention III relies on an RT-PCR method for the objective of reverse transcribing an RNA, whereas the method of invention IV relies on a phage display method for the objective of identifying a thermostable mutant polypeptide and the method of invention V relies on an *in vitro* screening and selection method to identifying a variant enzyme. The different inventions would constitute a search burden to the Examiner if searched together because the different searches are not coextensive. Specifically, methods of performing RT-PCR as recited in the invention of Group III is not required for or is necessary for performing phage display methods or enzyme screening and selection as required in the inventions of Groups IV and V and visa versa. As such the different inventions have non-overlapping subject and requires different fields of search. Thus, a serious search burden exist if the inventions are searched together.

3. Inventions I and III, IV and V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP

§ 806.05(h). In the instant case, the polynucleotide can be used in a materially different process such as in nucleic acid hybridization or in nucleic acid cloning and sequencing or in methods of differential display using microarray technologies. The different inventions would constitute a serious search burden to the examiner because the different inventions comprise non-overlapping subject matter and as such, the searches of the different inventions are not coextensive.

4. Inventions II and III, IV, V are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the polypeptide of Group II can be used in a materially different process such as in immunoprecipitation assays or in receptor/ ligand binding assays or in Western blotting procedures. The different inventions would constitute a serious search burden to the examiner because the different inventions comprise non-overlapping subject matter and as such, the searches of the different inventions are not coextensive.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the search required for each group is not required for the other groups because each group requires a different non-patent literature search due to each group comprising different products and/or method steps, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim

will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cynthia B. Wilder, Ph.D. whose telephone number is (571) 272-0791. The examiner can normally be reached on a flexible schedule.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on (571) 272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Cynthia B. Wilder, Ph.D.
Patent Examiner
Art Unit 1637

8/21/2006